UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge

MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION TO PRECLUDE DEFENSE EXPERT DAVID L. CHESNEY FROM OFFERING CLASS CERTIFICATION OPINIONS

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INTRODUCTION

Plaintiffs seek to exclude the expert opinions of David L. Chesney regarding defendant Zhejiang Huahai Pharmaceuticals' ("ZHP's") general compliance with the manufacturing standards established by the U.S. Food & Drug Administration ("FDA"). But rather than legal argument, the vast majority of Plaintiffs' brief consists of a list of hypothetical questions from Mr. Chesney's deposition in which Mr. Chesney was asked to assume that Plaintiffs had already proven highly contested facts in this case. Plaintiffs apparently hope that the Court will accept those hypotheticals as fact, resolve the disputed assumptions in Plaintiffs' favor, and exclude the opinions of Mr. Chesney as either irrelevant or unreliable on that basis. The Court should reject this improper strategy and deny Plaintiffs' motion.

First, Plaintiffs' two-sentence argument that Mr. Chesney's opinions are irrelevant and do not "fit" the facts of this case is meritless. Mr. Chesney's opinions regarding ZHP's regulatory inspection history and compliance with Good Manufacturing Practice ("GMP") bear directly on issues relevant to Rule 23, including, *inter alia*, whether Plaintiffs have put forth a valid damages model. Plaintiffs' contrary argument appears to be premised on the erroneous view that, to be relevant, Mr. Chesney's opinions must directly answer the legal question whether a class should be certified or whether particular Rule 23 requirements are satisfied.

Second, Plaintiffs challenge three of Mr. Chesney's opinions pertaining to ZHP's compliance with the FDA's GMP standards on the ground that they are unreliable or unsupported. This challenge also fails. Mr. Chesney's opinions on whether ZHP complied with the FDA's manufacturing standards in this case are well-supported by the FDA's own inspections finding ZHP in compliance with all relevant manufacturing principles. Nothing Plaintiffs point to in the record or in Mr. Chesney's deposition testimony suggests the contrary. And even if there were some contrary evidence or testimony from Mr. Chesney in the record, such evidence would only go to the weight that should be afforded to his opinions, not their admissibility.

For the foregoing reasons, Plaintiffs' motion should be denied in its entirety.

BACKGROUND

David L. Chesney is the Principal and General Manager of DL Chesney Consulting, LLC, a pharmaceutical and medical device regulatory consulting firm. (Expert Report of David L. Chesney ("Chesney Rep.") at 5, Jan. 12, 2022 (Pls.' Br. Ex. 5).) Mr. Chesney has 23 years of experience in the FDA as an FDA investigator, Supervisory Investigator, Director of Investigations and District Director. (*Id.* at 6-8.) He also has 26 years of experience in regulatory consulting, advising pharmaceutical, biotechnological and medical device companies in the areas of GMP, Medical Device Quality System Regulation, Good Clinical Practice, data

integrity and Pharmacovigilance/Medical Device Reporting compliance. (*Id.* at 8-9.)

During his time at the FDA, Mr. Chesney "conducted a wide range of investigations and inspections for the FDA, with an emphasis on . . . Good Manufacturing Practice," "personally participated in over 200 site inspections and had supervisory responsibility for hundreds of additional site inspections" and "signed over 400 Warning Letters and held many Regulatory Meetings with firms to resolve inspection-related matters." (*Id.* at 6-8.) As a consultant, Mr. Chesney similarly assists companies with issues related to GMP compliance, risk management, FDA interactions and responses to FDA enforcement activity. (*Id.* at 8-9.)

Mr. Chesney offers a series of opinions on ZHP's GMP compliance based upon his FDA experience and his review of FDA inspections and interactions with ZHP. (*Id.* at 2-5.) Specifically, Mr. Chesney reviewed the findings and subsequent actions of the FDA related to 13 different FDA inspections from 2010 to 2021 at two ZHP manufacturing sites, Xunqiao and Chuannan. (*Id.* 26-46.)

As Mr. Chesney explains in his report, from 2010 to August 2018, the FDA for the most part found no issues with ZHP's manufacturing sites as indicated by its lack of taking any significant action following the inspections. (*Id.* at 28-37.) Mr. Chesney concludes based on this lack of action that ZHP's facilities were "operating

in compliance with GMP at the time of th[ose] inspection[s]." (*Id.* at 29-31, 34, 36, 37.) On the few occasions when the FDA noted an issue following an inspection, Mr. Chesney details why each action did not indicate a violation of GMP and how the FDA's lack of escalation indicates that it did not find any evidence of GMP noncompliance. (*Id.* at 31-32, 34-36.)

It was not until an FDA inspection of the Chuannan site in November 2018 that the FDA took any significant action, culminating in a Warning Letter. (*Id.* at 37-41.) Although the FDA does not explain why this "for cause" inspection occurred, Mr. Chesney opines that it was triggered by the reported occurrence of NDMA in valsartan Active Pharmaceutical Ingredient ("API"). (*Id.* at 37.) Following the inspection, the FDA listed 11 different observations, of which ZHP contended only three actually related to the "occurrence of NDMA in Valsartan API." (*Id.* at 39.) Those three observations were related to an allegedly "inadequate change control system"; "sampling plans [that allegedly were] not always scientifically sound"; and "stability studies [that allegedly were] not always adequate." (*Id.* at 38-39.) ZHP challenged the factual accuracy of those three observations. (*Id.* at 39.) It also detailed the "reasonable, responsible steps taken by the company in reaction to confirming the presence of NDMA in Valsartan API," including: "(1) quarantin[ing] all Valsartan API in stock; (2) suspend[ing] release and distribution of Valsartan API; (3) stopp[ing] manufacturing [of] Valsartan API; (4) notif[ying]

all customers to place a hold on Valsartan API made by ZHP Huahai; and (5) notif[ying] the FDA on June 18, 2018, [and] requesting a meeting to obtain guidance from the FDA." (*Id.* at 39-40.)

Mr. Chesney likewise disputes the factual accuracy of the FDA's observations with regard to the "adequacy of ZHP's risk assessment." (*Id.* at 39, 53-55.) He notes that the FDA "offer[ed] no evidence nor clarification of how what ZHP did does not constitute a 'formal' risk assessment." (*Id.* at 53.) As Mr. Chesney's review revealed, ZHP's response to the FDA's observations demonstrated that ZHP did have an adequate risk assessment process in place because "(1) ZHP did have a formal SOP for change control, which included a requirement for assessment of risk; (2) records referenced in the response show ZHP followed their procedures; (3) the factors ZHP considered comprehensively address[ed] the risks posed by the proposed change and (4) the activities were documented." (*Id.* at 54-55 (footnotes omitted).) In any event, Mr. Chesney explains that the FDA's eventual Warning Letter Close Out Letter confirms "that the FDA was satisfied with the voluntary steps taken by ZHP in response to the Warning Letter." (*Id.* at 45-46.)

These opinions in Mr. Chesney's report are not cited once in the 16-page "Preliminary Statement" of Plaintiffs' brief. Instead, the brief cherry-picks various portions of Mr. Chesney's testimony given in response to largely irrelevant hypothetical questions premised on unfounded assumptions. Based on these out-of-

context snippets and unsupported hypotheticals, Plaintiffs falsely assert that "Mr. Chesney conceded that ZHP violated cGMPs and that the violations rendered the entire API manufacturing process to be in violation of cGMP," which "rendered all of the API made with that manufacturing process adulterated, and that the responsibility for this gross misconduct goes directly up the corporate ladder to ZHP Chairman Baohua Chen." (Pls.' Br. at 2; *id.* at 1-17.)

ARGUMENT

The standards governing the admissibility of expert testimony are set forth in Defendants' Opposition to Plaintiffs' Motion to Partially Exclude the Opinions of Timothy E. Kosty, and incorporated fully herein. As set forth below, Mr. Chesney's opinions easily satisfy these standards. First, Plaintiffs' argument that Mr. Chesney's opinions do not "fit" the facts of this case are baseless since Mr. Chesney's opinions bear directly on issues at the heart of the Rule 23 predominance inquiry. Second, Mr. Chesney's opinions are adequately supported by sufficient facts and data and are not contradicted by Mr. Chesney's testimony, and even if they were, such contradictions do not provide a basis for excluding his opinions here.

I. MR. CHESNEY'S OPINIONS "FIT" BECAUSE THEY ARE RELEVANT TO CLASS CERTIFICATION.

Plaintiffs first make the conclusory argument that Mr. Chesney's opinions should be precluded because he testified at his deposition "that he has no opinions with regard to class certification, parties other than ZHP, the TEA manufacturing

process, or finished dose products," and his opinions therefore do not "fit" into this case. (Pls.' Br. at 19.) This argument lacks merit. Mr. Chesney's opinions clearly "fit" the class certification issue because they bear directly on issues at the heart of whether Plaintiffs' proposed class meets the predominance requirement of Rule 23.

An expert's opinions fit the facts of a case under *Daubert* where they "assist the trier of fact to understand the evidence or to determine a fact in issue." *In re Niaspan Antitrust Litig.*, 464 F. Supp. 3d 678, 692 (E.D. Pa. 2020) (citation omitted). "Put another way," it is essentially "a question of relevance," and Rule 702 "has a liberal policy of admissibility" so long as an expert's opinion has the "potential for assisting the trier of fact." *United States v. Schiff*, 602 F.3d 152, 172-73 (3d Cir. 2010) (quoting *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 806 (3d Cir. 1997)).

At class certification, this means that "as long as the expert's opinion is relevant to one of the[] six elements needed for class certification," including predominance, "that opinion should be admissible." *Ancar v. Murphy Oil, U.S.A., Inc.*, No. 06-3246 et al., 2007 WL 3270763, at *1 (E.D. La. Nov. 2, 2007). Asking more of an expert—e.g., asking that the expert provide a legal opinion on whether a class is certifiable under Rule 23, as Plaintiffs suggest Mr. Chesney should do here—is not required; nor could it be, since such legal opinions are per se inadmissible. *See In re Mushroom Direct Purchaser Antitrust Litig.*, No. 06-0620, 2015 WL 5766930, at *2 (E.D. Pa. Aug. 20, 2015) ("Courts should exclude expert testimony

that goes solely to whether the legal standard for class certification has been satisfied.").

Mr. Chesney's opinions clearly satisfy this standard. From the face of Plaintiffs' motion, it is clear that Mr. Chesney's opinions "fit" the class certification question because, as Plaintiffs acknowledge, Defendants rely upon "Mr. Chesney's report three times in their class certification briefing." (Pls.' Br. at 19.) The opinions on which Defendants rely bear directly on issues relevant to whether Plaintiffs' proposed class can meet the predominance requirement of Rule 23. *See Ancar*, 2007 WL 3270763, at *1 (an expert's opinion "should be admissible" where it "is relevant to" predominance).

For example, Mr. Chesney's opinions on whether ZHP violated GMP are clearly relevant to whether the Valsartan-containing drugs ("VCDs") manufactured in this case was "adulterated." That issue not only relates to a key component of Dr. Conti's proposed damages model (*see, e.g.*, Pls.' Econ. Loss Br. at 69 (ECF 1748) (noting that Dr. Conti's valuation of VCDs relies on them being "non-compliant, adulterated and misbranded")), but also is at the heart of Plaintiffs' effort to paper over different variations in state laws that Defendants contend defeat predominance (*see, e.g.*, Pls.' Econ. Loss Reply Br. at 24 (ECF 2057) (Plaintiffs arguing that state law variations as to merchantability do not defeat class treatment of claims for breach

of implied warranty because an adulterated and recalled product is "***literally*** non-merchantable in every state")).

When the VCDs in this case became adulterated is also relevant to ascertainability because Plaintiffs define their class in part by "the period for which adulterated VCDs were on the market." (Pls.' Econ. Loss Reply Br. at 4.) In fact, Plaintiffs essentially admit in their motion that Mr. Chesney's opinions are directly relevant to whether their proposed class meets the requirements of Rule 23 since they note in their preliminary statement that ZHP's alleged GMP failures constitute "misconduct [that] is textbook for treatment on a class basis." (Pls.' Br. at 6.) Accordingly, Plaintiffs cannot seriously contend that Mr. Chesney's opinions do not fit the class certification questions.

Plaintiffs' suggestion that to satisfy the fit requirement, Mr. Chesney would have to opine on "parties other than ZHP, the TEA manufacturing process, or finished dose products" (Pls.' Br. at 19) is also plainly wrong. Plaintiffs do not even attempt to explain how Mr. Chesney's failure to opine on those issues would cause his clearly relevant opinions regarding ZHP's general compliance with GMP to not fit this case. Nor could they. After all, "[a]n expert's testimony is not made unreliable simply because it does not address certain issues." *Finjan, Inc. v. Sophos, Inc.*, No. 14-cv-01197-WHO, 2016 WL 4560071, at *4 (N.D. Cal. Aug. 22, 2016). Where an "expert report does opine on issues relevant to the class certification

motion in front of the [c]ourt," it is still helpful to the trier of fact even if it does not address other issues potentially relevant to class certification. *Tomeo v. CitiGroup, Inc.*, No. 13 C 4046, 2018 WL 4627386, at *6 (N.D. Ill. Sept. 27, 2018).

For all of these reasons, Plaintiffs' "fit" argument should be rejected.

II. MR. CHESNEY'S OPINIONS ARE SUFFICIENTLY SUPPORTED AND ARE NOT CONTRARY TO THE RECORD.

Plaintiffs next argue that Mr. Chesney's opinions are unreliable because they are either contradicted by statements he made in his deposition or were made without sufficient factual foundation. (*See* Pls.' Br. at 19-20.) Specifically, Plaintiffs contend that: (1) Mr. Chesney's opinion that ZHP did not fail to "conduct an 'adequate' risk assessment" is "self-serving" and "definitively contradicted by his sworn testimony"; (2) Defendants cannot rely on Mr. Chesney's opinion to support the conclusion that the "FDA did not declare any VCDs or API used to manufacture VCDs 'adulterated' until, at the earliest, November 29, 2018," because "ZHP's 2011 cGMP violation rendered all valsartan manufactured with [an] inadequately assessed process adulterated on a going forward basis"; and (3) Mr. Chesney's opinion that "[a]t all relevant times prior to each manufacturer's recall, all VCDs met their compendial and approved Drug Master File and ANDA specifications and their labeling conformed to the RLDs" is unsupported because Chesney "never reviewed the USP monographs for valsartan, and his report does not discuss ZHP's drug

master files or ANDAs for valsartan."[1] (*Id.* (citation omitted).) None of these attacks has merit.

First, Plaintiffs argue that the Court should exclude Mr. Chesney's opinion that ZHP did not fail to "conduct an 'adequate' risk assessment" because it is "self-serving" and "definitively contradicted by his sworn testimony." (Pls.' Br. at 19-20 (citation omitted).) That argument misstates the record by attempting to recast Dr. Chesney's answers to hypothetical questions as agreement with the flawed premises of Plaintiffs' questions.

Plaintiffs claim that Mr. Chesney agreed in his deposition "that the FDA's November 2018 Warning Letter to ZHP 'summarizes significant deviations from current good manufacturing practices (CGMP) for active pharmaceutical ingredients (API),'" including numerous ones concerning the inadequacy of ZHP's risk assessment. (Pls.' Br. at 19 (citation omitted); *see also* Dep. of David L. Chesney ("Chesney Dep.") 320:24-321:6, Mar. 21, 2022 (Pls.' Br. Ex. 1).) But Mr. Chesney did no such thing. Plaintiffs' counsel did not ask Mr. Chesney whether he ***agreed*** with the FDA's statements in its letter. Instead, counsel asked Mr. Chesney if "right

[1] Plaintiffs relatedly argue that Defendants improperly rely in their class certification briefing on Mr. Chesney to support their argument that ZHP did not "change[] its manufacturing process to 'save money' and 'dominate the world market share.'" (Pls.' Br. at 19 (citation omitted).) But Defendants do not rely on Mr. Chesney's report to support that argument in the footnote Plaintiffs reference. (*See* Defs.' Opp'n to Pls.' Econ. Loss Br. at 10 n.59 (ECF 2008).) The portion of Mr. Chesney's report that Defendants cite there goes to the adequacy of ZHP's risk assessment. (*See* Chesney Rep. at 53-59.)

there on the first page [of the letter] in the second sentence ***it says***, 'This warning letter summarizes significant deviations from current good manufacturing practice (CGMP) for active pharmaceutical ingredients (API),' right?" to which Mr. Chesney confirmed that is what the ***letter*** said. (Chesney Dep. 320:24-321:6 (emphasis added).)

To the extent Mr. Chesney agreed that anything in the letter could be considered a potential violation of GMP ***if*** it were accurate, he ***disputed*** the accuracy of those assertions in his deposition and explained that the letter does not constitute "the complete story" based on his review. (*See id.* 333:5-14 ("So this letter by itself makes certain assertions, but it's not the complete story."); *see also, e.g.*, *id.* 327:10-11 ("That's what the ***warning letter*** alleges, yes.") (emphasis added); *id.* 334:17-335:1 ("I don't agree [that the FDA felt that the process development study was inadequate and there was a violation of cGMP], and it's inconsistent with their public statements both before and after this warning letter. But that's what they say [in the letter].").) Mr. Chesney's disagreement with the findings of the FDA in its November 2018 Warning Letter is consistent with his report. (*See* Chesney Rep. at 39 ("However, in my opinion, as discussed below (pgs 53-55), the observations related to the adequacy of ZHP's risk assessment are flawed."); *id.* at 53-59.)

Plaintiffs' claim that, "when confronted with scientific literature supporting the inadequacy of ZHP's risk assessment" and other materials apparently relevant to

ZHP's risk assessment obligation, "Mr. Chesney confirmed, '[T]his would be the type of feasibly available scientific information you would expect the people at ZHP to have been aware of when they were performing the risk assessment with regard to their decision to add DMF to the manufacturing process'" (Pls.' Br. at 19 (citation omitted); *see also id.* at 6-16) is likewise false. Again, Mr. Chesney never agreed with Plaintiffs that ZHP's alleged failure to consider that information rendered its risk assessment inadequate or violated GMP. As Mr. Chesney explained at his deposition, such a finding "requires a multifaceted consideration" encapsulating more than just a single factor such as whether ZHP reviewed certain pieces of scientific information. (Chesney Dep. 149:20-151:1; *see also* Chesney Rep. at 1-2 ("Whether a product meets [GMP] calls for a multidisciplinary approach . . . . The field does not lend itself to simplistic requirements that are easily interpreted and applied.").)

In fact, when specifically asked by counsel whether he would find ZHP in violation of GMP if he assumed that ZHP "never took [the scientific information] into account," Mr. Chesney ***denied*** that he would. (Chesney Dep. 146:21-148:10.) Rather, to find a GMP violation based on the availability of that scientific information would require multiple levels of assumptions, including not only the assumption that ZHP never considered that information, but also the "assum[ptions] that considering that [scientific] information could have feasibly led to testing to see

if nitrosamines were being formed . . . and that testing would have shown NDMA was being formed." (*Id.* 151:3-152:4.) Each of those assumptions is unsupported by the record, and their validity was disputed by Mr. Chesney at his deposition. Based on the other information Mr. Chesney reviewed, the evidence "suggests that, at least from the FDA's public statements . . . that technology was not up to speed until much later," and "[n]either the regulators nor the industry at large really had" the awareness Plaintiffs would ask Mr. Chesney and the Court to assume. (*Id.* 151:12-19; *see also id.* 113:24-114:6 (Mr. Chesney describing his "concern[] about the validity of some of these assumptions" because "the FDA in their public statements later on indicated that the general awareness of these risks wasn't really known in the industry or even to the regulators until much later").) Indeed, "the full awareness and understanding didn't really occur until sometime in the middle of 2018" (*id.* 152:18-153:3), and the "bits and pieces of the total story" that Plaintiffs put forth did not cause Mr. Chesney to agree that ZHP violated GMP (*id.* 151:24-152:4).

Even accepting Plaintiffs' misleading assertion that Mr. Chesney's "deposition testimony does in fact contradict the opinion expressed in his expert report, that is a matter which [would go] to the weight, not the admissibility, of his opinion and [could] be explored on cross-examination." *Tuft v. Indem. Ins. Co. of N. Am.*, No. 19-cv-01827-REB-KLM, 2021 WL 1037863, at *3 (D. Colo. Jan. 29,

2021). Courts routinely hold that where an expert testifies in a deposition in a manner that is contradictory to his report, those inconsistencies go to the weight afforded to the expert's opinion, not its admissibility. *See, e.g.*, *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, No. 17-cv-5096 (WMW/BRT), 2020 WL 5512507, at *7-8 (D. Minn. Sept. 14, 2020) (denying motion to exclude expert opinion where party identified "inconsistent or contradictory positions between [expert]'s expert reports and [expert]'s deposition testimony" because "[s]uch inconsistences are matters for cross-examination, not grounds for exclusion"), *aff'd*, 30 F.4th 1339 (Fed. Cir. 2022); *Buddy's Plant Plus Corp. v. CentiMark Corp.*, 978 F. Supp. 2d 523, 533 (W.D. Pa. 2013) ("That [expert] . . . allegedly contradicted himself in his expert report and deposition affects the weight and credibility of [his] testimony, and not to his qualifications or methods used to support his opinion."), *aff'd*, 604 F. App'x 134 (3d Cir. 2015). Accordingly, even assuming that Mr. Chesney's deposition testimony contradicted his report, such contradictions would not be sufficient grounds to exclude his opinions.

Second, Plaintiffs' argument that Mr. Chesney should not be allowed to opine that the "FDA did not declare any VCDs or API used to manufacture VCDs 'adulterated' until, at the earliest, November 29, 2018" (Pls.' Br. at 20 (citation omitted)) should also be rejected. Plaintiffs offer no basis for this argument other than their own belief that the VCDs or API ***should have been*** declared adulterated.

But whether a drug is "adulterated" is a classification that is only bestowed by the FDA, and it is not the province of an expert witness to rewrite regulatory history. *See* 21 U.S.C. § 351(a)(2)(B); Dep. of Roger Williams, M.D. 206:1-16, Feb. 17, 2022 (Ex. 1); Chesney Rep. at 49; *see also, e.g.*, *Robinson v. Ethicon, Inc.*, No. H-20-03760, 2022 WL 614919, at *6 (S.D. Tex. Mar. 2, 2022) (holding that expert "cannot take the final step of opining that the product was 'misbranded' or 'adulterated,' as these are impermissible legal conclusions"). There is no basis to prevent Mr. Chesney from offering this opinion.

Even if Plaintiffs were able to usurp the FDA's role here, their entire argument that ZHP violated GMP and rendered the VCDs "adulterated" again rests on assumptions and hypotheticals. The key piece of testimony Plaintiffs cite in their motion is a response to a question asking Mr. Chesney whether he "agreed that 'If you make the ***assumption*** . . . as to the inadequacy of the risk assessment, . . . and the risk assessment violated GMP, . . . it [would] be a violation of GMP to'" manufacture the VCDs in that way. (Pls.' Br. at 20 (emphasis added) (citation omitted).) But Mr. Chesney made it clear when responding to that question "that [he was] not accepting the assumptions" Plaintiffs proposed and was, instead, "viewing them purely as hypotheticals." (Chesney Dep. 114:22-115:3.) Similarly, his report explicitly states that ZHP was compliant with GMP throughout the FDA inspections prior to November 2018, and refutes the notion that ZHP did not conduct

an adequate risk assessment. (*See* Chesney Rep. at 29-31, 34, 36, 37; *id.* at 53-55 (describing ZHP's risk assessment process and concluding that, in Mr. Chesney's opinion, "a formal risk assessment was in fact done").)

Third, Plaintiffs are incorrect that Mr. Chesney's opinion that "[a]t all relevant times prior to each manufacturer's recall, all VCDs met their compendial and approved Drug Master File and ANDA specifications and their labeling conformed to the RLDs" is unsupported because Mr. Chesney "never reviewed the USP monographs for valsartan, and in his report does not discuss ZHP's drug master files or ANDAs for valsartan." (Pls.' Br. at 20 (citation omitted).) This contention erroneously assumes that an expert must review every scrap of potentially relevant data before forming an opinion. Rule 702 only requires that expert testimony be "based on sufficient facts or data." Fed. R. Evid. 702(b); *see also Grande Vill. LLC v. CIBC Inc.*, No. 1:14-cv-3495 (NLH/JS), 2018 WL 3085207, at *4 (D.N.J. June 22, 2018). The fact that an expert "did not review all of the materials" that Plaintiffs contend are relevant to a case "is not a basis to exclude [the expert]'s testimony," though it may be appropriate fodder for cross-examination. *Grande Vill. LLC*, 2018 WL 3085207, at *4; *see United States v. Evers*, No. 3:19-CR-250, 2021 WL 3710735, at *10 (M.D. Pa. Aug. 20, 2021) (contention that an expert did not review every possible material in a litigation "goes to the weight of the opinion rather than the admissibility").

Mr. Chesney offers more than sufficient foundation for his challenged opinions. As Mr. Chesney explains in his report, once there is "a specification . . . in place" for a drug, "either via a compendial monograph revision or approval of an NDA, ANDA, or supplement thereto, and there are findings that demonstrate such specification is not met, then adulteration" is established. (Chesney Rep. at 18, 47-48.) And at no point prior to the recall throughout the FDA's multiple inspections of the ZHP facilities or through other sources were the VCDs considered "adulterated" by the FDA. (*See* Chesney Rep. at 28-37.)

Accordingly, Mr. Chesney's opinions are reliable and based on sufficient facts and data, and Plaintiffs' arguments to the contrary should be rejected. *See Benham v. Ozark Materials River Rock, LLC*, No. 11-CV-339-JED-FHM, 2013 WL 5592975, at *3 (N.D. Okla. Oct. 10, 2013) (admitting expert's opinions based on the "inspection reports of the agencies" and those agencies' lack of finding any violations of the Clean Water Act).

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiffs' Motion To Preclude Defense Expert David L. Chesney From Offering Class Certification Opinions.

Dated: June 2, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on June 2, 2022, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ *Jessica Davidson Miller*
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